JUL 3 1 2003

510(k) Summary

Submission Information

Name and Address of Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401
For Information contact:	Margaret F. Crowe Regulatory Affairs Consultant Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401

Device Identification

Proprietary Name:	Global Modular Replacement System Pediatric Tibial Bearing Component
Common Name:	Modular Rotating Hinge Knee System
Classification Name and Reference:	Knee joint femorotibial metal/polymer constrained cemented prosthesis 21 CFR §888.3510
Proposed Regulatory Class:	Class II
Device Product Code:	OR(87) KRO

Intended Use

The Global Modular Replacement System (GMRS™) Pediatric Tibial Bearing Component is intended to be used to mate the distal femoral components of the Global Modular Replacement (GMRS™) System or the femoral components of the Modular Rotating Hinge (MRH) System to the Pediatric All Polyethylene Tibial Components of the Modular Replacement System The indications for use for the GMRS™ Pediatric Tibial Bearing Component are listed below:

Indications

Replacement of the distal femur and/or proximal tibia in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where

radical resection and replacement of the bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications. This smaller size component is intended to be used in patients with a smaller bone structure, or in skeletally immature patients. This component is intended to be implanted using bone cement.

Contraindications

A. As related to Bone Tumors

Not all bone tumors may be treated successfully by segmental resection. Any condition that may have already resulted in either local or distant spread of the tumor may be a contraindication. Examples of such conditions include:

- pathological fracture;
- overt infection;
- inopportune placement of biopsy incision; and,
- rapid disease progression beyond a respectable margin.

B. As related to Failed Previous Prosthesis and Trauma

- Any active or suspected latent infection in or about the affected joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complication in postoperative care.
- Bone stock compromised by disease, infection, or prior implantation that cannot provide adequate support and fixation of the prosthesis.

Device Description

The GMRS™ Pediatric Tibial Bearing Component is a single use device that is available in one size. The GMRS™ Pediatric Tibial Bearing Component is designed to mate with the all sizes of the femoral components of the GMRS™ or the MRH systems, and the MRS pediatric all poly tibial components. The design of this GMRS™ Pediatric Tibial Component is similar to the design of the existing MRH XS/XL Tibial Bearing Component - this component is stemmed, and connects to the femoral component by a set

of bushings and an axle. A bumper locks this assembly. In terms of dimensions, the subject The GMRS™ Pediatric Bearing has a smaller distal stem diameter, and reduced anterior-posterior and medio-lateral dimensions when compared to the MRH XS/XL Tibial Bearing Component. These reduced dimensions are identical to those seen in the MRS Pediatric Tibial Bearing Component.

Equivalent products include the MRS Pediatric Tibial Bearing Component (Howmedica Osteonics Corp.) and the MRH Crossover Tibial Bearing Component (Howmedica Osteonics Corp.).

Finite element analysis (FEA) was presented to support a claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2003

Mr. William J. Cymbaluk
Vice President, Quality Assurance/Regulatory Affairs/Clinical Research
Howmedica Osteonics Corp.
59 Route 17 South
Allendale, New Jersey 07401

Re: K031480
Device Name: Global Modular Replacement System (GMRS™) Pediatric Tibial Bearing Component
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: May 9, 2003
Received: May 12, 2003

Dear Mr. Cymbaluk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GMRS™ Pediatric Tibial Bearing Component 510(k) Premarket Notification
Confidential

510(k) Number (if known): K 031480

Device: GMRS™ Pediatric Tibial Bearing Component

The Global Modular Replacement System (GMRS™) Pediatric Tibial Bearing Component is intended to be used to mate the distal femoral components of the Global Modular Replacement (GMRS™) System or the femoral components of the Modular Rotating Hinge (MRH) System to the Pediatric All Polyethylene Tibial Components of the Modular Replacement System The indications for use for the GMRS™ Pediatric Tibial Bearing Component are listed below:

Indications

Replacement of the distal femur and/or proximal tibia in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of the bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications. This smaller size component is intended to be used in patients with a smaller bone structure, or in skeletally immature patients. This component is intended for use with bone cement.

Contraindications

A. As related to Bone Tumors

Not all bone tumors may be treated successfully by segmental resection. Any condition that may have already resulted in either local or distant spread of the tumor may be a contraindication. Examples of such conditions include:

- pathological fracture;
- overt infection;
- inopportune placement of biopsy incision; and,
- rapid disease progression beyond a respectable margin.

B. As related to Failed Previous Prosthesis and Trauma

for Mark A. Miller
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K 031480

- Any active or suspected latent infection in or about the affected joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complication in postoperative care.
- Bone stock compromised by disease, infection, or prior implantation that cannot provide adequate support and fixation of the prosthesis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the Counter-Use_____ (per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031486